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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,175	10/31/2003	John R. Bianchi	MSDI-434/PC316.08	1020
52196	7590	11/05/2007		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER GHERBI, SUZETTE JAIME J	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 11/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/699,175

Applicant(s)

BIANCHI ET AL.

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 72-135 and 249-361 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 135 is/are allowed.
- 6) ☒ Claim(s) 72-134, 269-361 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Applicant's after final remarks filed 10/18/07 have been received in application serial number 10/699,175.

### *Specification*

The amendment filed 12/17/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body. Applicant is referred to MPEP 2125 which states:

PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int 'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."). However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. In *re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and Bauer's drawing figures, that Bauer clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel.' This ignores the fact that Bauer does not disclose that his drawings are to scale. ... However, we agree with the Solicitor that Bauer's teaching that whiskey losses are influenced by the distance the liquor needs to traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)" would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey losses." 569 F.2d at 1127, 193 USPQ at 335-36.)

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Applicant is therefore required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **72-134, 249-361** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular in claims 72, 91 and 111, 249 and 292 recite a range of “....*less than approximately one-half of the width of the adjacent vertebral bodies*” and this range constitutes new matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 72, 91 and 111, 134, 249, 269, 292 are rejected under 35 U.S.C. 102(e) as being anticipated by Pafford et al. 6,371,988. Pafford et al. discloses the invention as *claimed noting figures 7, 24 and 47-49 and as best interpreted* comprising:

An interbody spinal implant (40) made of cortical bone (col. 6, lines 43-48) for insertion at least in part into an implantation space formed across the height of a disc space between adjacent vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect comprising:

a leading end (48) , a trailing end (26') opposite the leading end, wherein the implant has a length along a mid-longitudinal axis of said implant from the leading end to the trailing end; opposed upper and lower portions (*the upper portion is the tooled beveled space shown in figures 47-49 and the lower is interpreted as opposite of the beveled end*) between the leading and trailing ends said upper and lower portion being non-arcuate along at least a portion of the length of the implant (**see col. 7, lines 64-65 which discloses that the crest 44 of each tooth 43 is flat**); an interior facing side, an exterior facing side opposite the interior side, and a maximum width there between capable of being less than approximately one-half of the width of the adjacent vertebral bodies (see fig. 24 interior side is right and exterior side is left); said interior and exterior sides connecting the upper and lower portions and said leading and trailing end, said leading end having a generally straight portion (straight slot including hole 49 for tool) from side to side, said interior side (*see fig. 24 where interior side of one of the implants*

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*is to the right) forming a corner (the tooled bevel side and the straight slot for the tool form this corner) with said generally straight portion of the leading end; said implant being manufactured from a bone ring obtained from a major long bone of a human having a medullary canal* are interpreted as Product by Process and are not limited to the manipulations of the recited steps only to the structure implied by the steps (see MPEP 2113).

***Allowable Subject Matter***

Claim 135 is allowed.

***Response to Arguments***

Applicant contends that claims 135 and 269-291 were not identified in the prior office action. These claims have been addressed supra.

It is noted that the manufacturing steps recited in the claims are being treated as Product by process limitations see MPEP 2113

Applicant's arguments filed 10/18/07 with regards to the new matter have been fully considered and have been explained in the prior office action as recapped below.

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On pages 2 of the remarks, applicants contends that the previous examiner did not point out or provide grounds for rejection and further did not address the remarks from the reply dated 12/4/06.

It is admitted that the grounds of rejection were maintained in the office action dated 3/419/07. It is the applicants right to believe that the previously submitted arguments support the patentability of the pending claims. On page 3 of the current remarks applicant further states that an interview was conducted with the previous examiner and that they reiterated the same ground of rejection and provided supplemental comments that were not provided in the May 7, 2007 office action.

In response to this comment no statutory period will be restarted. See MPEP, which states:

Where the citation of a reference is incorrect or an Office action contains some other defect and this error is called to the attention of the Office within 1 month of the mail date of the action, the Office will restart the previously set period for reply to run from the date the error is corrected, if requested to do so by applicant. See MPEP § 710.06.

The current examiner will now address the reiteration of the prior arguments as stated on page 4 of the current remarks.

Applicant contends that the specification supports the wording "...said upper and lower portions being non-arcuate along at least a portion of the length of the implant. The examiner has further reviewed the specification and agrees that support for this claim language is found in applicant's specification in col. 8:43-51 or section [0078]. Therefore the 112 rejections with regards to the limitations "...said upper and lower

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portions. being non-arcuate along *at least a portion of the length of said implant...*" has been withdrawn.

Turning to page 7 of applicants current remarks, applicant contends the new matter objection and 112 rejections for the limitations "...each of dowels having a width less than approximately one-half of the width of the adjacent body.." Here applicant continues to argue the dimensions of the drawings and provides case law. These arguments are not found persuasive and have been addressed *supra*..nevertheless the MPEP states that the drawings are not to scale and one of ordinary skill in the art would not make the assumption of measurements as each implant may be placed in an anatomy of varied proportion for example the claims do not limit the implants from only being utilized in human patients. The drawings are just mere examples and could for instance to manipulated to fit any variety of situations.

With regards to the art rejection of patent '125, ;955 applicants, applicant is not entitled to its claim of priority due to the new matter rejections as mention *supra*.


### ***Conclusion***

This is a RCE of applicant's earlier Application No. 10/699,175. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

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even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

  
SUZETTE GHERBI  
PRIMARY EXAMINER  
TECHNOLOGY CENTER 3700

30 October 2007